IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **WAVE 4 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF SCOTT A. GUELCHER, PH.D.

Defendants Ethicon, Inc., Ethicon LLC, and Johnson & Johnson (collectively, "Ethicon") submit this memorandum in support of their motion to exclude the opinions and testimony of Scott A. Guelcher, Ph.D. This motion applies to the cases listed in Ex. A.

ARGUMENT

I. Legal Standard

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at **1-3, (S.D. W. Va. July 8, 2014).

II. Dr. Guelcher's Opinions Regarding Alternative Designs Are Unreliable.

In his report, Dr. Guelcher proposes a number of different procedures and materials as alternatives to the Ethicon mesh products at issue in this litigation. Ex. B, Guelcher Report at 21-23. Specifically, Dr. Guelcher asserts that procedures involving the use of sutures—including the Burch procedure and needle suspension procedure—and biological grafts are alternatives that do not present the same risks as Ethicon mesh products. *Id.*

Although Dr. Guelcher's proposals are alternative *treatment options*, they do not constitute feasible and safer alternative *designs* for Ethicon mesh products. Moreover, Dr. Guelcher has not supported his opinions with reliable testing or scientific literature demonstrating that his proposed alternatives are both safer and equally as efficacious as the Ethicon mesh products at issue. Indeed, Dr. Guelcher failed to account for a large body of medical literature that is inconsistent with Guelcher's alternative design opinions.

A. Dr. Guelcher's proposed alternative procedures and materials do not constitute alternative designs.

As this Court has recognized, the issue of alternative design with respect to pelvic mesh products "must be examined in the context of products—not surgeries or procedures." Mem. Op. and Order, *Mullins v. Johnson & Johnson*, 2:12-cv-02952, at 3 (S.D. W. Va. Feb. 23, 2017) [ECF 1881] ("*Mullins* Order"). This is because "alternative surgeries or procedures concern the medical judgment of the doctors" who use the device at issue; "other surgeries or procedures do not inform the jury on *how* the [device at issue]'s design could have feasibly been made safer to eliminate the risks that caused the plaintiff's injuries." *Id.* at 4; *see also Hilaire v. DeWalt Indus. Tool Co.*, 54 F. Supp. 3d 223, 248 (E.D.N.Y. 2014) ("A plaintiff cannot satisfy his burden to propose a feasible alternative design by proposing that an entirely different product could have been used."). The same logic controls in this litigation.

None of the alternatives proposed by Dr. Guelcher constitutes a proper alternative design to the Ethicon mesh products at issue in this litigation. Indeed, two of the alternatives advocated by Dr. Guelcher—the Burch procedure and needle suspension procedures—do not involve any device specially indicated for the treatment of SUI or POP. Rather, both alternatives are completely different procedures in which the only device at issue is a simple surgical suture. This Court has expressly rejected such procedures as alternative designs. *Mullins* Order at 4-5.

Likewise, the remaining alternatives proposed by Dr. Guelcher—autografts, allografts, and xenografts—cannot be considered alternative designs to Ethicon mesh products. As an initial matter, an autograft is not even a medical device; it is a graft fashioned by the surgeon from the patient's own harvested tissue. More importantly, none of these biological grafts utilize any type of mesh or synthetic material, and each is implanted and functions differently than Ethicon mesh products.

At bottom, Dr. Guelcher's opinion is that mesh is defective because it undergoes oxidative degradation *in vivo* and elicits an increased foreign body reaction, meaning that no medical device composed of synthetic material for the treatment of SUI or POP is an appropriate treatment option. Other federal courts have rejected the argument that alternative treatment options that completely avoid the use of the allegedly defective medical device constitute safer alternative designs for that device. *See, e.g., Theriot v. Danek Medical, Inc.*, 168 F.3d 253 (5th Cir. 1999).

The product at issue in *Theriot* was a pedicle screw indicated for the treatment of spinal problems, and the plaintiff's proposed alternative designs were "other products that do not use pedicle screws[.]" *Id.* at 255. The trial court granted summary judgment in favor of the manufacturer on plaintiff's design defect claim due to lack of an alternative design. The Fifth Circuit affirmed, noting that "[u]nderlying [plaintiff's] argument is the assumption that all pedicle screws are defective and there can be no system using pedicle screws that would be an acceptable product." *Id.* The Fifth Circuit recognized, as this Court did in *Mullins*, that "[t]he problem with this argument is that it really takes issue with the choice of treatment made by [plaintiff's] physician, not with a specific fault of the pedicle screw sold by [manufacturer]." *Id.*

Similarly, the assumption underlying Dr. Guelcher's alternative design opinions is that any product for the treatment of SUI or POP that uses mesh is defective, and that Plaintiffs' treating physicians should recommend alternative surgical treatment options for their patients. Ex. B, Guelcher Rep. at 21 (opining that sutures and biological grafts are safer alternatives because such procedures and materials do "not present with the same chronic complications associated with the material properties of the [] mesh.").

For these reasons, none of Dr. Guelcher's proposed alternatives actually constitutes an alternative design to Ethicon mesh products, and the Court should preclude him from offering such opinions at trial. *See Mullins* Order, at 3-5; *Schmidt v. C.R. Bard, Inc.*, 2013 U.S. Dist. LEXIS 101963, at *6 (D. Nev. July 22, 2013) ("[N]on-mesh repair is not an alternative design and does not meet Plaintiff's burden to support [a design defect claim]."); *Michael v. Wyeth, LLC*, No. 2:04-cv-0435, 2011 WL 2150112 at *11 (S.D. W. Va. 2011) ("[A]n alternative design must not be an altogether essentially different product.").

B. Dr. Guelcher's alternative design opinions are unreliable.

Even assuming *arguendo* that Dr. Guelcher's proposed alternatives could be construed as alternative designs in this litigation, the Court should nevertheless preclude him from opining as to these proposed alternatives because his opinions are unreliable.

1. Expert opinions regarding alternative designs must be supported by testing or scientific literature demonstrating that the proposed alternative is actually safer.

As the Fourth Circuit recently explained in *Nease v. Ford Motor Co.*, an expert's alternative-design opinion must be excluded under *Daubert* if the expert failed to establish, using reliable testing or scientific literature, that the alternative design is actually safer. 848 F.3d 219 (4th Cir. 2017). The plaintiff in *Nease* crashed a truck he was driving because he was unable to stop, allegedly due to the "mechanical binding" of the truck's speed-control cable. *Id.* at 221-23.

The plaintiff's expert proposed three alternative designs to the speed-control cable which purportedly would have prevented the accident. *Id.* at 234. The court noted that the expert based his opinions on the fact that the manufacturer had used "all of these alternative design features [in other vehicles] for many years by the time the [truck] was produced." *Id.*

The Fourth Circuit held the expert's alternative design opinions were unreliable because they were unsupported by testing or scientific literature. *Id.* The court had previously explained that while *Daubert* is a "flexible test" and no single factor is dispositive, "[o]ne especially important factor for guiding a court in its reliability determination is whether a given theory has been tested." *Id.* at 231.[1] As the court observed, in the absence of supportive testing or scientific literature, an expert's theory may be plausible and "may even be right[,] . . . [but] it is no more than a hypothesis, and thus is not knowledge, nor is it based upon sufficient facts or data or the product of reliable principles and methods applied reliably to the facts of the case." *Id.*

Applying these principles, the court found that the expert "performed no tests or studies to determine whether, in fact, these older, long-standing designs were involved in fewer binding incidents." *Id.* at 234. The expert similarly "offered no data from any other studies or accident records to prove that the older designs were less likely to bind than the one incorporated" in the truck. *Id.* Rather, the expert "simply proclaimed without any support that the alternative designs he identified were safer than the design of the speed control cable assembly in the [truck]." *Id.*

For these reasons, the court concluded that the "testimony should have been excluded as it was unsupported by any evidence such as test data or relevant literature in the field." *Id.* (citation omitted). Importantly, the court explained that the "fact that the [proposed] alternatives

[1] Applying the *Daubert* factors, the court had excluded the expert's opinion that the speed-control cable was defective because (i) he "conducted no testing whatsoever to arrive at his opinion"; (ii) he failed to publish or otherwise subject his theory to peer review; (iii) his poor "methodology" rendered it impossible to determine a potential rate of error; and (iv) a company document identifying potential failure modes did not constitute "general acceptance" of the expert's theory. *Id.* at 232-33.

have generally been in use for decades is wholly insufficient to prove that such designs were safer" in the context of the accident at issue, or "that reasonably prudent manufacturers would have adopted them." *Id.*

In applying the teachings of *Nease* to Dr. Guelcher's opinions, it is clear that the Court should exclude his alternative design opinions for the same reasons. As an initial matter, Dr. Guelcher has not conducted any testing on any of the alternative procedures and materials he proposes. *See* Ex. B, Guelcher Report at 21-23. In addition, as discussed in greater detail below, none of the literature to which he cites actually establishes that the alternatives he proposes would be safer—and at least as effective at treating SUI or POP—as the Ethicon mesh products at issue in this litigation. *See id.*

2. Dr. Guelcher's failed to support his alternative design opinions with scientific literature.

Dr. Guelcher does not cite any authority that supports his assertion that suture-based repairs like the Burch procedure are safer or as effective as Ethicon mesh products. *Id.* at 21-22. Rather, he refers only to a handful of articles addressing the foreign body reaction to sutures and mesh, but none of which actually demonstrate that suture-based repairs are safer or as effective as Ethicon mesh products in treating SUI or POP. Like the expert in *Nease*, despite this lack of support, Dr. Guelcher "simply proclaims" that treatments involving sutures are "preferred" because they elicit "less persistent" foreign body reaction than mesh, and "do not present the risk of mesh-related complications." *Id.* at 22.

Although Dr. Guelcher seeks to base his opinion that biological grafts are safer and as effective as Ethicon mesh products on three studies, a review of these studies demonstrates that they simply do not support his opinion. *See* Ex. B, Guelcher Report at 22-23; *see also* Ex. C, S. Crivellaro, *et al.*, "Transvaginal Sling Using Acellular Human Dermal Allograft: Safety and

Efficacy in 253 Patients, 172 J. Urology 1374-78 (2004); Ex. D, S.L. Brown & F.E. Govier, "Cadaveric Versus Autologous Fascia Lata for the Pubovaginal Sling: Surgical Outcome and Patient Satisfaction," 164 J. Urology 1633-37 (2000); Ex. E, B.J. Flynn & W.T. Yap, "Pubovaginal Sling Using Allograft Fascia Lata Versus Autograft Fascia for All Types of Stress Urinary Incontinence: 2-Year Minimum Followup," 167 J. Urology 608-12 (2002).

As an initial matter, Dr. Guelcher made no effort to support his proposed alternative designs for Ethicon mesh products used to treat POP. The Brown and Flynn studies do not address any device used to treat POP in any way. And while some of the procedures reported on in the Crivellaro study involved both POP and SUI repairs, the study did not actually report on complications or efficacy with respect to POP. *See* Ex. C, Crivellaro. Because none of the studies on which Dr. Guelcher relies actually address POP, he should not be permitted to offer alternative design opinions with respect to Ethicon mesh products used to treat POP.

In addition, the only sources Dr. Guelcher relies on for his opinions regarding biological grafts are three dated and relatively short-term studies which offer no support for the long-term safety and efficacy of biological grafts. By the authors' respective admissions, each of these studies is relatively short term. Ex. C, Crivellaro at 1377 ("Longer followup and a randomized trial comparing Repliform to other materials used in sling procedures are needed."); Ex. E, Flynn at 612 (explaining that results do not justify adoption of different pubovaginal sling material "until long-term data are available and reproducible by multiple groups"); Ex. D, Brown, at 1636 (noting that results must "remain consistent at longer followup"). Given that none of the studies is recent—with the latest being published in 2004—Dr. Guelcher's decision to base his opinions on short-term studies is telling. Because Dr. Guelcher cannot say that his alternatives offer viable

long-term safety and efficacy rates, he should not be able to offer his proposals as alternative designs to Ethicon mesh products.

Highlighting the weakness of Dr. Guelcher's methodology is the fact that the author of one of these studies—Dr. Brian Flynn—has opined in this litigation that biological grafts are not safer or more effective than Ethicon mesh products. *See* Ex. F, Expert Report of Brian J. Flynn, M.D. (TVT) ("Flynn TVT Report"); Ex. G, Expert Report of Brian J. Flynn, M.D. (Prolift) ("Flynn Prolift Report"). Based on his experience and review of the literature in the fourteen years since the article on which Dr. Guelcher relies was published, Dr. Flynn now concludes that while biological grafts can be used to treat SUI and POP, they do not have better safety and efficacy rates than Ethicon mesh products. *See* Ex. F, Flynn TVT Report at 12 (concluding that allografts—like Repliform—"do not have the long-term durability of synthetic material," and "have been shown to degrade and decompose in patients on follow up."); Ex. G, Flynn Prolift Report at 12 (explaining that systematic literature reviews have shown that biological grafts cause exposure, wound complications, and dyspareunia at rates comparable or even exceeding synthetic mesh). Dr. Flynn also observes that biological grafts present risks of unique complications (including tissue rejection and the transmission of diseases) that are not associated with synthetic mesh. Ex. G, Flynn Prolift Report at 13.

Finally, as discussed below, in basing his opinions on three relatively old, short-term studies, Dr. Guelcher ignored the substantial body of literature demonstrating that his proposed alternatives are not, in fact, safer or at least as effective as Ethicon mesh products.

3. Dr. Guelcher failed to account for a vast body of contrary scientific literature.

As this Court has recognized, an "expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead selectively [chooses] his support from the

scientific landscape." *Sanchez v. Bos. Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *11 (S.D. W. Va. Sept. 29, 2014). If "the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable." *Id*.

Dr. Guelcher's alternative design opinions are unreliable because he failed to "acknowledge or account for" the significant volume of medical literature demonstrating that Ethicon's mesh devices are as safe or safer than his proposed alternatives.[2] Similarly, his opinion that non-mesh alternatives are safer because they eliminate the risk of "mesh-related complications" (*i.e.*, mesh exposure) is unreliable because it is well-known and reported in the medical literature that exposure and wound complications are not complications unique to mesh.[3]

[2] *See, e.g.*, Ex. H, A. Woodruff, *et al.*, "Histological comparison of pubovaginal sling graft materials: a comparative study," 72 Urology 85-89 (2008) (histologic comparison various grafts finding (i) autologous and cadaveric fascia explants had the "most demonstrable graft degradation"; (ii) xenografts were all "severely encapsulated," (iii) "cadaveric tissues demonstrated the most degradation of all harvested materials, as well as mild to moderate encapsulation"; and (iv) polypropylene mesh explants "displayed no evidence of degradation or encapsulation[.]"); Ex. I, M. Albo, *et al.*, "Burch colposuspension versus fascial sling to reduce urinary stress incontinence," 356 N. Eng. J. Med. 2143-55 (2007) (comparing outcomes from autologous slings to Burch procedure, and reporting overall incidence of "serious adverse events" as 13% in the autologous sling group and 10% in the Burch group, while non-serious adverse events were reported as 63% and 47%, respectively); Ex. J, B. Welk, *et al.*, "Removal or revision of vaginal mesh used for the treatment of stress urinary incontinence," JAMA Surg. (2015) (analysis of 58,887 patients treated with synthetic slings—such as Ethicon's TVT and TVT-O—revealed overall 10-year cumulative rate of complications of only 3%).

[3] *See, e.g.*, Ex. K, A. Sokol, *et al.*, "One-year objective and functional outcomes of a randomized clinical trial of vaginal mesh for prolapse," 206 Am. J. Obstet. Gynecol. 86.e1-9 (2012) (randomized controlled trial comparing outcomes in patients undergoing surgical prolapse repairs with mesh versus non-mesh repairs utilizing sutures, and reporting 15.6% rate of mesh exposure against 15% rate of suture exposure); Ex. L, H. Abed, *et al.*, "Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review," Int. Urogynecol. J. (2011) (systemic review of 110 studies addressing incidence of synthetic and biological graft erosions in prolapse repairs, and finding rate of erosion was 10.3% in the synthetic grafts and 10.1% in the biological grafts); Ex. M, T. Yazdany & N. Bhatia, "Suture complications in a teaching institution among patients undergoing uterosacral ligament suspension with permanent braided suture," 21 Int. Urogynecol. J. 813-18 (2010) (reporting 44.6% rate of suture-related complications, with a 36.1% incidence of suture erosion, in patients undergoing a non-mesh prolapse repair); Ex. N, M. Toglia & M. Fagan, "Suture erosion rates and long-term surgical outcomes in patients undergoing sacrospinous ligament suspension with braided polyester suture," 198 Am. J. Obstet. Gynecol. 600.e1-4 (2008) (reporting 36% suture-related complication rate in patients undergoing a non-mesh prolapse repair, with 25% of those patients undergoing suture removal).

Finally, the medical literature demonstrates that Dr. Guelcher's proposed alternatives do not offer greater efficacy rates than Ethicon mesh products. For example, the medical literature shows that synthetic slings, such as TVT and TVT-O, provide superior long-term efficacy compared to the Burch procedure and pubovaginal slings constructed with allografts and autografts.[4]

Ultimately, Dr. Guelcher failed to demonstrate—through testing or scientific literature—that his proposed alternative designs are safer or at least as effective as Ethicon mesh products. Accordingly, Dr. Guelcher's alternative design opinions are unreliable, and should be excluded by this Court. *See Nease*, 848 F.3d at 234.

III. Dr. Guelcher's Opinions Concerning Ethicon's Purported Knowledge, State of Mind, and Corporate Conduct Do Not Assist the Trier of Fact.

Throughout his Report, Dr. Guelcher opines as to Ethicon's alleged knowledge regarding a variety of topics. *See, e.g.*, Ex. B, Guelcher Report at 3, 15, 17, 21. In support of these opinions, Dr. Guelcher spends several pages of his Report presenting his interpretation of a series of Ethicon's internal documents. *See id.* at 14–18, 21. This Court has repeatedly held that a corporate defendant's "knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony

[4] *Compare* Ex. O, C. Nilsson, *et al.*, "Long-term Follow-up of the TVT operation: 17 year results," 24 Int. Urogynecol. J. Supp. S1-152, 107 (2013) (reporting 17-year data for women treated with TVT, and showing 93% objective cure rate) *and* Ex. P, R. Svenningsen, *et al*, "Long-term follow-up of the retropubic tension-free vaginal tape procedure," Int. Urogynecol J. (2013) (reporting 89.9% objective cure rate for 10-year follow up on 483 patients treated with TVT) *with* Ex. I, Albo (reporting cure rate of 66% for patients treated with autologous slings, and 49% for patients treated with Burch procedure) *and* Ex. Q, F. Demirci, *et al.*, "Long-term results of Burch colposuspension," 51 Gynecol. Obstet. Invest. 243-47 (2001) (reporting 87.7% cure rate at 1.5 years, which declined to 77.4% by the mean 4.5-year follow-up period) *and* Ex. R, P. Kjolhede, "Long-term efficacy of Burch colposuspension: a 14-year follow-up study," 84 Acta Obstet. Gynecol. Scand. 767-72 (2005) (reporting that 14 years after Burch procedure, 19% of patients remained completely dry, and 56% demonstrated significant SUI).

because opinions on these matters will not assist the jury." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013).[5] The result here should be no different.

CONCLUSION

For these reasons, Ethicon respectfully requests that the Court grant its Motion to Exclude the Opinions and Testimony of Dr. Scott Guelcher.

Respectfully submitted,

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[5] Dr. Guelcher is also unqualified to opine as to Ethicon's corporate knowledge and conduct. He is a chemical engineer. His resume does "not include knowledge or even experience in the manner in which corporations and the [medical device] marketplace react, behave or think regarding their non-scientific goals of maintaining a profit-making organization that is subject to rules, regulations, standards, customs and practices among competitors and influenced by shareholders or public opinion." *In re Diet Drugs Prods. Liab. Litig.*, No. MDL 1203, 2000 WL 876900, at *9 (E.D. Pa. June 20, 2000). He is thus unqualified to opine as to Ethicon's corporate conduct.

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CERTIFICATE OF SERVICE

I hereby certify that on April 13, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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